

Section 1

Community Consultation and Public

Disclosure Plan approved by

Institutional Review Board (IRB)

Community Consultation and Public Disclosure (CCPD) Plan
Johnson City Medical Center
Principal Investigator – Julie Dunn, M.D.

RTBSE-11-N: A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting

I. Purpose of Plan

The purpose of this plan is to describe the methods by which the communities of Johnson City, Jonesborough, and Washington County will be notified regarding the aforementioned clinical research trial. In order to conduct this trial, an exception from informed consent requirements has been requested and approved in accordance with 21 CFR §50.24: *Exception from informed consent requirements for emergency research*. As stated in 21 CFR §50.24, community consultation and public disclosure must occur prior to patient enrollment. Community consultation will include an outpouring of information to ensure that the local public is fully informed of the purpose of the study and the potential benefits and risks involved in study participation. Information will be disseminated in a variety of ways and will include, but may not be limited to: presentations and discussions in public forums, as well as print, broadcast and electronic media (Internet). Minutes of each meeting, including questions or comments posed by community members, will be recorded. Copies of public notices and transcripts from broadcast media will also be documented and made available to ETSU/VA Medical Campus Institutional Review Board for review. Upon conclusion of this trial, study findings will be made available to the public via print and broadcast media. The study sponsor, Northfield Laboratories Inc (Evanston, IL), will bear the cost of implementing this plan and will assist in the preparation and execution of this plan. Additionally, the ETSU/VA Medical Campus Institutional Review Board will review the progress of this plan in accordance with 21 CFR §50.24.

II. Timing of Plan

Community Consultation will take place prior to the enrollment of patients in this clinical trial. The conclusions of this study will be reported to the public within 30 days after data collection is complete, data is analyzed and validated, and the results are made available to the investigator.

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III. Target Audience and Location

The target audience for consultation will be based on the overall makeup of our trauma population, according to demographic data compiled by our trauma registry.

IV. Communication Methods

- Internal Communication (Hospital Staff and Paramedics)
 - ☒ Departments of Surgery, Anesthesiology, Emergency Medicine and Critical Care Nursing will have attended a presentation by Dr. Julie Dunn. In addition, this presentation will be videotaped, and made available for distribution to all employees as reference. For those unable to attend, information will be made available by study personnel attending department meetings.
 - ☐ Paramedic Division will execute inservices for each paramedic potentially involved in the trial. *The Paramedic Supervisor, John Reeves, CCEMPT; Clinical Coordinator Julie A. Dunn, M.D.; and Study Coordinator, Andrea Hyde, R.N., B.S.N.* will carry out this education process. Principal and co-investigators will indirectly supervise this process.
- External Communication (Community)
 - ☒ A public notice will be placed in local print news publications, and will include locations and times of public meetings and investigator contact information.
 - ☐ Internet access will be provided as a link on the Mountain States Health Alliance and East Tennessee State University websites to distribute information and a create forum for comments and questions via Email.
 - ☒ The Principal Investigator, study personnel and Joe Smith, who is a representative of the ETSU/VA Medical Campus Institutional Review Board will attend informational forums, including focus groups, community meetings and city council meetings. The general public will be invited to attend these meetings. Study fact sheets containing general information about the trial and a question and comment section will be made available. A contact phone number, mailing address and Email address will be provided as well. Dialogue will be encouraged and questions, concerns and comments will be documented and provided to the ETSU/VA Medical Campus Institutional Review Board.

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- ✓ Aggressive media will be conducted. We plan to conduct an initial press conference on October 19, followed by an opportunity for the media to interview the Principal Investigator. Dr. Julie Dunn, who is the PI, will also participate in an editorial board meeting with the major local newspaper to engage their support. A combined media campaign will be led by James Watson of the MSHA Communications team and Joe Smith of ETSU University Relations. Both have worked with the Tri-Cities media for several years and maintain very strong and positive relationships with the press. Local print and broadcast media, including appropriate ethnic and age specific media will be targeted.

V. Study Information to be Disseminated

- Background and purpose of the study using multimedia presentations and handouts.
- General study procedures
- Risks and benefits of the study
- Emphasis on waiver from informed consent information
- Right to refuse and method to indicate refusal

VI. Specific Routes to Community Awareness

- Local Print Media - Print media has long been considered a legal and appropriate means by which the public may be notified. The following publications were chosen based on either their wide or appropriately targeted distribution and / or diversity of political and social readership. Print media to be targeted will include, but may not be limited to:
 - ✓ Johnson City Press, The Loafer, Kingsport Times-News, Elizabethton Star, News and Neighbor
- Broadcast Media - Local media will be used to reach the public by via conventional news coverage and interviews with Principal Investigator. Television and radio stations to be targeted will include, but may not be limited to:
 - ✓ WJHL Newschannel 11 (CBS); WCYB Newscenter 5 (NBC); WKPT (ABC); WETS-FM 89.5 (NPR); Tri-Cities Radio Group; Holston Valley Broadcasting; and all major FM and AM radio stations in the region

VII. Approval

- This plan is to be submitted by Dr. Julie Dunn on behalf of ETSU and Johnson City Medical Center and reviewed by ETSU/VA Medical Campus Institutional Review Board in conjunction with the protocol application dated October 12, 2004. Additionally, investigators will summarize the progress and completion of community consultation described herein, and submit this summary to ETSU/VA Medical Campus Institutional Review Board for their

review prior to the enrollment of any patients in this clinical trial. Northfield Laboratories Inc. will submit this plan and final summary to the FDA as required by 21 CFR § 50.24.

VIII. Timeline

- Investigator proposes that community consultation efforts begin within one week following the approval of ETSU/VA Medical Campus Institutional Review Board to do so. Community consultation will last approximately one month, and a summary report will follow within 30 days.

IX. Unforeseen Encumbrance

- Investigator will conduct this outreach effort in accordance with the spirit of the community consultation guidance of the FDA and ETSU/VA Medical Campus Institutional Review Board. However, it is possible that unexpected obstacles may be encountered in the course of such a complex undertaking. Any major changes and corrective action taken will be submitted to ETSU/VA Medical Campus Institutional Review Board in writing and in a timely fashion.

X. Feedback

- Point of contact for comments or concerns regarding this plan will be directed to the study coordinator and / or Principle Investigator:

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